

16/B



ATTORNEY'S DOCKET NUMBER: 10010313-1 (2003309-0012)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yakhini *et al.* Examiner: Nickol, Gary B.
Serial No.: 09/921,406 Art Unit: 1642
Filing Date: August 2, 2001
Title: CLASSIFYING CANCERS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RECEIVED
JUL 25 2003
TECH CENTER 1600/2900

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the Restriction Requirement mailed May 20, 2003, in the above-referenced case, Applicant elects Group I (claims 1-4), as drawn to a method of diagnosing an aggressive form of cancer comprising providing a genetic sample from a test sample of a tumor and analyzing expression of Wnt5a, classified in class 425, subclass 6.

However, Applicant makes this election of Group I with traverse. Applicant respectfully submits that in order for a restriction to be proper the following two criteria must be satisfied: (a) the inventions must be independent or distinct as claimed; and (b) there must be a serious burden on the examiner if restriction is required. MPEP § 803. The claimed invention of diagnosing an aggressive form of cancer is based on determining the expression of a collection of genes chosen from the genes recited in claim 1. Applicant submits that part of the inventors' contribution to the art was identifying the set of genes listed in claim 1, as important in diagnosing aggressive forms of cancer. Therefore, the breadth of patent protection necessary for adequate coverage of the inventors' contribution to the art must include a claim including all twenty genes. The examiner, however, maintains that testing for the expression of each of the genes listed in the Markush group of claim 1 is a separate invention, thereby yielding *twenty* inventions within the first *two* claims of the present application. Applicant submits that these are not independent and distinct inventions because a patent to a single species does not give the applicant the breadth of coverage recognized by

the inventors in analyzing for the expression of a collection of genes selected from the Markush group.

Also, Applicant respectfully submits that searching multiple genes does not place a serious burden on the examiner. MPEP section 803.02 on restriction of Markush claims states that "if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent inventions." As evidence that the restriction in this case is not proper, Applicant wishes to point out that groups I-XX all fall within the same field of art, *i.e.*, class 435, subclass 6. Applicant requests that all the genes recited in the Markush group of claim 1 be examined as one invention or that the Applicant be allowed to pick a smaller collection of genes to include in the Markush group for examination.

It is Applicant's understanding that there are no fees associated with this matter. Should this understanding be in error, please charge any fees that may be required, or credit any overpayments, to Deposit Account No. 50-1078.

Respectfully submitted,



C. Hunter Baker, M.D., Ph.D.
Registration No. 46,533

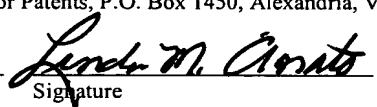
Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5000
Dated: July 21, 2003

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

July 21, 2003

Date



Signature

Linda M. Amato

Typed or Printed Name of person signing certificate